

VITAMIN, MINERAL, AND OTHER PRODUCTS OF SPECIAL DIETARY SIGNIFICANCE

27394. Decavitamin tablets. (F.D.C. No. 45512. S. No. 12-748 R.)

QUANTITY: 1,008 1,000-tablet btls. at Hines, Ill.

SHIPPED: 12-21-60, from Oak Park, Mich.

RESULTS OF INVESTIGATION: Examination showed that the article contained approximately 50 percent of the declared amount of vitamin B₁₂.

LIBELED: 3-10-61, N. Dist. Ill.

CHARGE: 402(b)(1)—while held for sale, the valuable constituent, vitamin B₁₂, had been in part omitted or abstracted from the article; and 403(a)—the label statement "Vitamin B-12 2 Mcgs." was false and misleading.

DISPOSITION: 4-11-61. Consent—claimed by Freshman Vitamin Co., Oak Park, Mich.; reprocessed and relabeled.

27395. Gestatabs. (F.D.C. No. 45908. S. No. 14-219 R.)

QUANTITY: 37 60-tablet btls. and 1 1,000-tablet btl. at Chicago, Ill.

SHIPPED: Between 1-16-60 and 11-18-60, from Kenilworth, N.J., by White Laboratories, Inc.

LABEL IN PART: (Btl. and ctn.) "Gestatabs A Unique, Comprehensive Dietary Supplement Designed Especially For Use During Pregnancy and Lactation. Contains Essential Vitamins and Minerals Plus Mol-Iron. * * * White Laboratories, Inc., Kenilworth, New Jersey * * * Each Tablet Contains: * * * Folic Acid 0.5 mg. * * * Dosage: One Gestatab twice daily."

LIBELED: 5-31-61, N. Dist. Ill.

CHARGE: 402(a)(2)(C)—when shipped, the article contained a food additive, namely, folic acid, which is unsafe within the meaning of 409 since it and its use, or intended use, were not in conformity with a regulation or exemption in effect pursuant to 409.

DISPOSITION: 6-30-61. Default—destruction.

27396. Orogen tablets. (F.D.C. No. 44669. S. Nos. 11-716/8 R.)

QUANTITY: 15 cases, 12 200-tablet btls. each, 15 cases, 12 100-tablet btls. each, and 4 cases, 12 400-tablet btls. each, at Chicago, Ill., in possession of Mandel Bros., Inc.

SHIPPED: Between 3-4-57 and 4-9-57, from Portland, Oreg., by Consumer Drug Corp.

LABEL IN PART: (Btl.) "Orogen Dietary Aid with Pectolex. Contains natural substances from citrus fruits as a result of pharmaceutical research by Sun-kist Growers. Orogen Distributors Consumer Drug Corp., Portland, Oregon."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately one percent of the declared amount of vitamin B₁₂.

LIBELED: 6-17-60, N. Dist. Ill.

CHARGE: 402(b)(1)—while held for sale, the valuable constituent, vitamin B₁₂, had been in whole or in part omitted or abstracted from the article; 403(a)—the label statement "Daily Dose (6 tablets) provides * * * Vitamin B-12 Activity from Cobalamin Concentrate 0.6 mg." was false and misleading as applied to the article which contained less than the declared amount of vitamin B₁₂; and when shipped, the label statement "The minimum daily re-

quirement for Niacinamide * * * have not been established" was false and misleading since the minimum daily requirement for niacinamide has been established, and the label of the article also contained false and misleading representations and suggestions that the article was adequate and effective for appetite appeasement; and 403(j)—when shipped, the article purported to be and was represented as a food for special dietary use by reason of its vitamin content and its label failed to bear, as required by regulations, a statement of the proportion of the minimum daily requirement for niacinamide when consumed in a specified quantity during a period of one day.

DISPOSITION: 7-14-61. Consent—destruction.

27397. Preg-Nine tablets. (F.D.C. No. 45928. S. No. 69-311 R.)

QUANTITY: 144 100-tablet btls., 1 500-tablet btl., and 2 1,000-tablet btls., at Chicago, Ill.

SHIPPED: 6-11-59, from Indianapolis, Ind.

LABEL IN PART: (Btl.) "Preg-Nine Each tablet represents: * * * Folic Acid 0.250 mg. * * * Four tablets provide * * * One tablet four times daily * * * Manufactured for Rasman Pharmacal Co. Oak Park, Illinois."

RESULTS OF INVESTIGATION: The article was repacked and labeled by Rasman Pharmacal Co., Oak Park, Ill., from bulk drums shipped as described above, and then reshipped to the dealer at Chicago, Ill., between 11-5-59 and 4-19-61.

LIBELED: 6-5-61, N. Dist. Ill.

CHARGE: 402(a) (2) (C)—while held for sale, the article contained a food additive, namely, folic acid, which is unsafe within the meaning of 409 since it and its use, or intended use, were not in conformity with a regulation or exemption in effect pursuant to 409.

DISPOSITION: 7-10-61. Default—destruction.

27398. Honey Al-Fa Tea. (F.D.C. No. 44913. S. No. 23-315 R.)

QUANTITY: 29 16-oz. btls. and 22 32-oz. btls. at Oklahoma City, Okla.

SHIPPED: 8-1-60 and 9-12-60, from Dallas, Tex., by Honey Al-Fa Pharmaceutical Co.

LABEL IN PART: (Btl.) "Concentrated Honey Al-Fa Tea * * * Homogenized * * * Especially pressed, extracted, and brewed from rich Alfalfa components. Also contains Proteins, Amino Acids (Arginine, Histidine, Lysine, Humin, Saponin, and natural enzymes) Plus Pure Bee Honey and Apple Cider Vinegar."

ACCOMPANYING LABELING: Leaflets entitled "A Reader's Digest Reprint Concentrated Honey Al-Fa Tea" and "For Your Vitamins Concentrated Honey Al-Fa Tea."

LIBELED: 9-27-60, W. Dist. Okla.

CHARGE: 403(a)—when shipped and while held for sale, the labeling of the article contained the false and misleading statement "rich with homogenized concentrated vitamins"; 403(e) (2)—the article failed to bear a label containing an accurate statement of the quantity of contents; and 403(j)—the article purported to be and was represented as a food for special dietary use by reason of its vitamin and mineral content and its label failed to bear, as required by regulations, a statement of the proportion of the minimum daily requirement for the vitamins and minerals supplied by such food when consumed in a specified quantity during a period of one day.